Consumer Advocates in Peer Review:

Things You Need To Know About Cancer Clinical Trials



NATIONAL CANCER INSTITUTE

2005

Objectives

- Name the types and phases of clinical trials.
- Describe the importance of including women, minorities, and children in clinical trials.
- Identify barriers that deter specific groups from participating in research studies.
- Explore methods for recruiting minority groups as participants in clinical and population research studies.

What are cancer clinical trials?

- Research studies to find better ways to prevent, detect, or treat cancer
- Help doctors find ways to improve cancer care

NATIONAL CANCER INSTITUTE

Who participates in cancer clinical trials?

- Less than 5% of all eligible people with cancer
- Few over age 65
- Fewer underrepresented populations

Why should we care?

- Cancer affects all of us
- Each year in the U.S.A:
  - More than half a million people are expected to die of cancer — more than 1,500 people a day
  - Minorities are disproportionately affected by cancer

Why should we care?

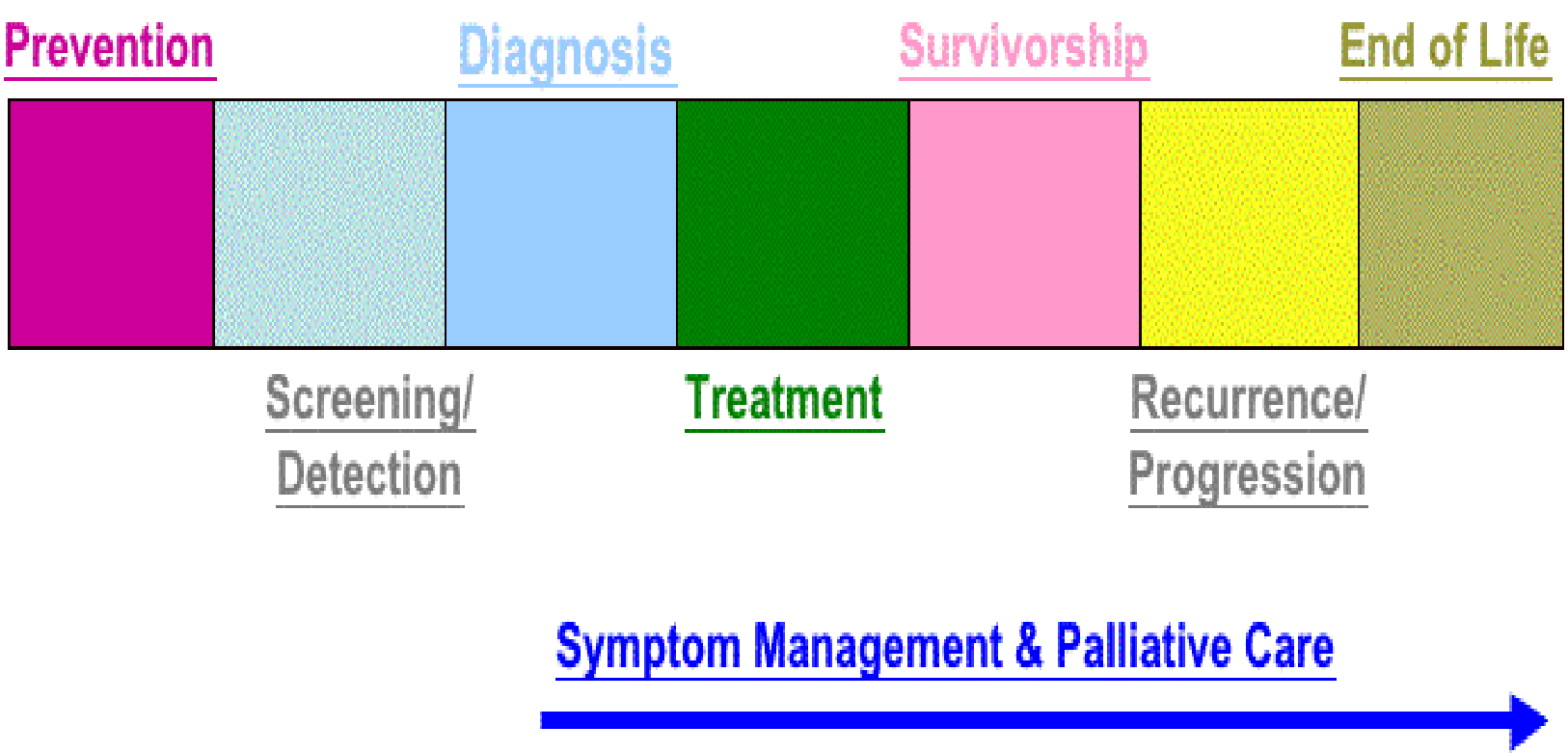
- Clinical trials translate results of basic scientific research into better ways to prevent, diagnose, or treat cancer

- The more people that take part, the faster we can:
  - Answer critical research questions
  - Find better treatments and ways to prevent cancer

There are five different types of clinical trials.

- Prevention
- Screening/early detection
- Diagnostic
- Treatment
- Quality of life/supportive care

Clinical Trials Across the Cancer Continuum



Cancer Prevention Trials

- For healthy people at risk of developing cancer
- Action studies vs. agent studies
- Possible benefit:
  - Early access to new interventions
- Possible risk:
  - Unknown side effects and effectiveness

Screening and Early-Detection Trials

- Assess new means of detecting cancer earlier in healthy people
- Possible benefit:
  - Detecting disease at an earlier stage, resulting in improved outcomes
- Possible risks:
  - Discomfort and inconvenience
  - If imaging technique is studied, exposure to x-rays or radioactive substances

Diagnostic Trials

- Develop better tools for classifying types and phases of cancer and managing patient care
- Possible benefits:
  - New technology may be better and less invasive
  - Earlier detection of recurrences
- Possible risk:
  - May require people to take multiple tests

Cancer Treatment Trials

- What new treatments can help people who have cancer?
- What is the most effective treatment for people who have cancer?
- Placebos “sugar pills” are seldom used in cancer treatment trials

NATIONAL CANCER INSTITUTE

Quality-of-Life/ Supportive Care Trials

- Aim to improve quality of life for patients and their families
- Possible benefit:
  - Early access to new treatment
- Possible risk:
  - May not benefit from participation

Clinical Trial Phases

- Phase 1 clinical trials: 15-30 people
  - What dosage is safe?
  - How should treatment be given?
  - How does treatment affect the body?
- Phase 2 clinical trials: Less than 100 people
  - Does treatment do what it is supposed to?
  - How does treatment affect the body?

Clinical Trial Phases

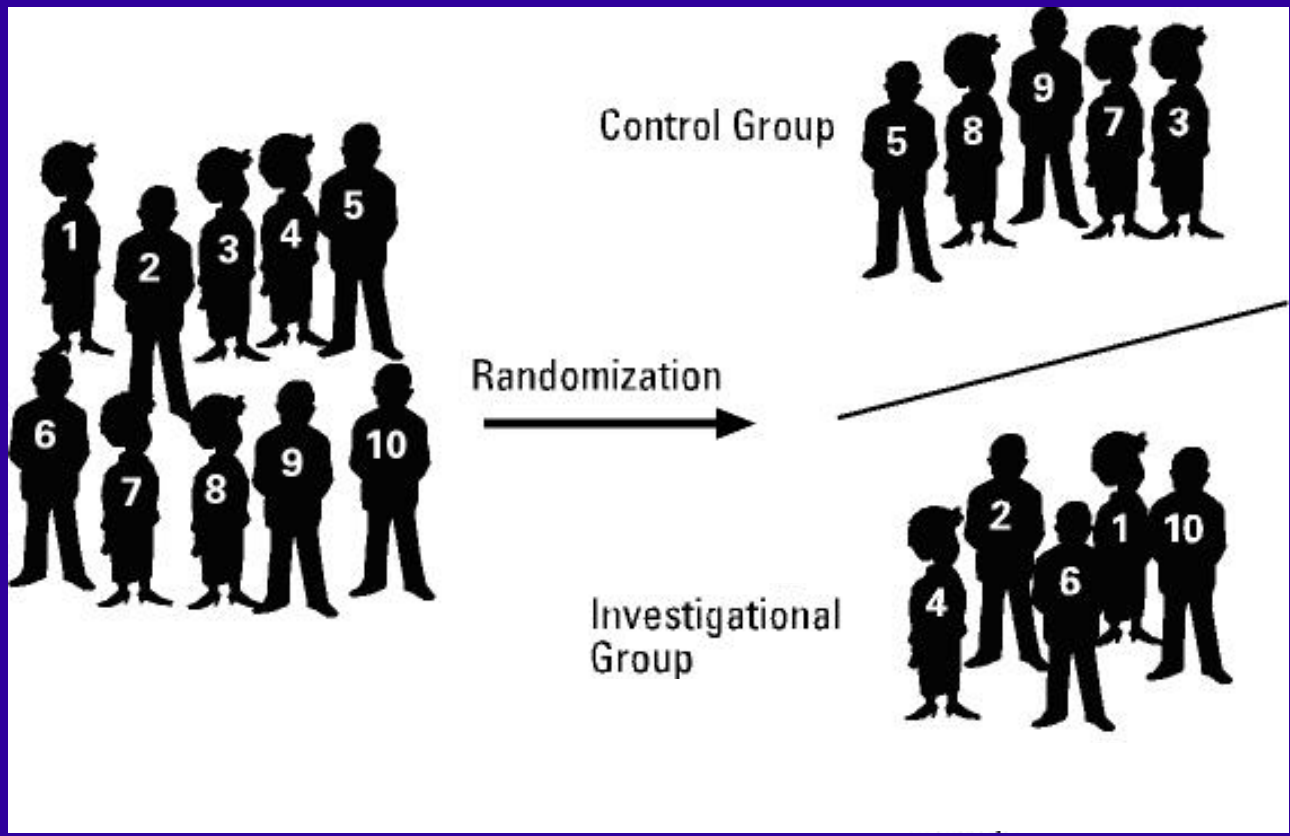
- Phase 3: From 100 to thousands of people
  - Compare new treatment with current standard
- Phase 4: From hundreds to thousands of people
  - Usually takes place after drug is approved
  - Used to further evaluate long-term safety and effectiveness of new treatment

Participants are often randomized.

All have an **equal chance** to be assigned to one of two or more groups:

- One gets the most widely accepted treatment (standard treatment)
- The other gets the new treatment being tested, which researchers hope and have reason to believe will be better than standard treatment

Randomization



There are benefits and risks.

Possible benefits:

- Patients will receive, at a minimum, the best standard treatment
- If the new treatment or intervention is proven to work, patients may be among the first to benefit
- Patients have a chance to help others and improve cancer care

There are benefits and risks.

Possible risks:

- New treatments or interventions under study are not always better than, or even as good as, standard care
- Even if a new treatment has benefits, it may not work for every patient
- Health insurance and managed care providers do not always cover clinical trials

There are laws protecting patients safety.

- There were past abuses in patient protection
- Federal regulations ensure that people are told about the benefits, risks, and purpose of research before they agree to participate

Why do so few people with cancer participate in clinical trials?

Sometimes patients:

- Don’t know about clinical trials
- Don’t have access to clinical trials
- May be afraid or suspicious of research
- Can’t afford to participate
- May not want to go against physician’s wishes

Why do so few people with cancer participate in clinical trials?

Doctors might:

- Lack awareness of appropriate clinical trials
- Be unwilling to “lose control” of a person’s care
- Believe that standard therapy is best
- Be concerned that clinical trials add administrative burdens

Clinical Trials: More Information

- NCI Web site: www.cancer.gov
  http://cancer.gov/clinicaltrials/learning
- Cancer Information Service
  - 1-800-4-CANCER or TTY: 1-800-332-8615
  - www.cancer.gov/cis
- Clinical Trials Education Promotion
  - www.ncipoet.org/CTES/index.cfm

NATIONAL CANCER INSTITUTE